

## **REMARKS**

Claims 1, 3-20, and 22-30 are currently pending in the application. Claim 20 is canceled herein. Claims 1, 17, and 27 are in independent form.

Applicants wish to express their appreciation for the courtesies extended Applicants' representative, Dr. Kenneth I. Kohn, during a personal interview with the Examiner on December 9, 2010. During the interview, the rejection of the previous Office Action was discussed in view of the previously submitted Amendment. It was suggested that Applicants file a Supplemental Amendment that further defined the orientation of the lumens as being coaxial in each of the independent claims. Clarification of the position of the body portion and neck portion was also proposed. It was agreed that the proposed amendments appear to distinguish the invention over the prior art of record. Accordingly, Applicants have amended each of the independent claims, as discussed in detail below.

Claim 1 has been amended to better define the invention. Support can be found for the amendments as follows:

"A trocar comprising a body portion operatively connected to a neck portion, said neck portion including an insert end" – see paragraph [0037].

"...said trocar including an instrument lumen within said chamber for receiving an instrument therethrough said instrument lumen extending from an opening in said body portion to said insert end of said chamber ending at said sealing means" – see paragraph [0045].

"and a downflow lumen extending from said body portion to an outlet port proximate to said instrument lumen and said body portion including an inlet port fluidly connected to said downflow lumen for enabling flow of an inert fluid from said

downflow lumen into said instrument lumen about an instrument extending therethrough and out of an inlet port in said body portion.” – see paragraphs [0046] and [0047].

These amendments have been added to more clearly define the structure of the trocar that allows for an inert fluid to remove any air bubbles that may be trapped within the instrument lumen so that no air is allowed to enter the bloodstream of a patient. No new matter has been added.

Claim 1 stands objected to for informalities. This objection has been rendered moot in view of the above amendments.

Claims 17-25 stand rejected under 35 U.S.C. §112, second paragraph as being indefinite. Specifically, claim 17 has insufficient antecedent basis for “the trocar”. In response thereto, claim 17 has been amended to recite “a trocar”. Claim 20 is held to be unclear. In response thereto, claim 20 has been canceled without prejudice. Reconsideration of the rejection is respectfully requested.

Claims 1, 3, 5-10, 14, and 15 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,788,676 to Yoon in view of U.S. Patent No 5,993,471 to Riza, et al., and further in view of U.S. Patent No. 4,180,068 to Jacobsen, et al. Specifically, the Office Action holds that Yoon discloses a trocar having an insert end with a housing wherein a pair of universal seals are positioned in the proximal and distal ends of the chamber to provide an air and fluid tight seal when engaging or not engaging an instrument but fails to disclose perpendicular diaphragms, and Riza, et al. teaches two deformable diaphragms having slits that are perpendicular with respect to one another. The combination of Yoon and Riza, et al. fails to disclose a downflow lumen having an outlet opening into an instrument lumen and an inlet port opposite thereto. The Office Action holds that Jacobsen, et al. discloses a trocar including lumens disposed therein for irrigation of fluid through a downflow lumen, a lumen in

which the instrument is disposed, an inlet port that is opposite to an outlet opening that opens only into the instrument lumen. Therefore, the Office Action holds that it would have been obvious to one skilled in the art to provide consecutive diaphragms having perpendicular slits to enhance sealing structure and to provide the device with a downflow lumen, as taught by Jacobsen, et al. to simultaneously introduce and withdraw fluids from the body of a patient. Reconsideration of the rejection under 35 U.S.C. §103(a), as being unpatentable over Yoon in view of Riza, et al. and Jacobsen, et al. is respectfully requested.

"Any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed"; however, that reason must be present for the combination to be obvious. *KSR Intern Co. v. Teleflex*, 127 S. Ct. 1727, 1742, U.S. (2007). This requirement was confirmed in *Takeda Chem. Indust., et al. v. Alphapharm*, No. 06-1329 (Fed. Cir. 2007).

"The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396 (2007) noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit." MPEP Section 2143.

"The rationale to support a conclusion that the claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination yielded nothing more than predictable results to one of ordinary skill in the art." *KSR International Co. v. Teleflex Inc.*, 83 UDPQ2d 1385, 1395 (2007) and MPEP Section 2143.

As previously stated, the goal of the device of Yoon is to prevent damage to universal seals by preventing contact with instruments when they are inserted or withdrawn in the endoscopic portal. More specifically, the universal seals 16a and 16b are "disposed in the main body 26 in axially spaced relation to one another." Col. 6, lines 3-4. In other words, the universal seals are in alignment with one

another in order to let an instrument through the portal. One seal is opened allowing passage of the instrument while the other seal remains closed to prevent leakage into the portal. Yoon does not disclose seals that are perpendicular to each other instead of aligned with each other as in the present invention. Yoon further does not disclose a downflow lumen. Yoon does not provide any reason to add these features to his device.

Applicants agree that Riza discloses a split seal 44 and a second seal defining a plane which is perpendicular to the plane defined by the slit 52 of the split seal 44 that provides an enhanced sealing structure for a shaft of a surgical instrument inserted through both of the split seals. (Col. 7, lines 50-57).

Jacobsen, et al. discloses a "single-tube double-lumen catheter through which fluids may be simultaneously introduced into and withdrawn from the body of a patient." Col. 2, lines 1-6. Tubes 8 and 12 communicate with primary tube 2 through openings 9 and 13 on the primary tube. Between the branching tube 8 and the distal end of the primary tube 2 is an opening 20 in the wall of the primary tube that allows fluid to flow from the body of the patient into the primary tube. A trocar 24 divides the interior of the primary tube 2 into two lumens 25 and 27. Looking at Figures 1-4 of Jacobsen, et al., it is evident that ***the device cannot function as required in the present invention.*** Figure 1 shows the catheter in an insert position, i.e. when no fluid is able to flow through. Figure 2 shows the catheter when fluid is allowed to flow through the primary tube 2, exiting into the patient, or fluid from the patient is allowed to flow into opening 20 and through tube 8 of the catheter. At no time when fluid is allowed to flow into or out of the catheter is it blocked from contact with the patient. Adding the lumens of Jacobsen, et al. to the combination of Yoon and Riza, et al. would function in the opposite manner of the present invention. The lumens of Jacobsen, et al. are not separate from the instrument lumen, and are only formed when the trocar is present, or an instrument is present, in the primary tube. ***The lumens are also not used to flow fluid through the instrument lumen to remove***

***harmful substances, but rather are open to the patient through openings 9 and 20 in order to deliver fluid to or remove fluid from the patient. This is completely opposite to the function of the downflow lumen in the present invention.*** Fluid could not be used to remove substances in the instrument lumen of Jacobsen, et al. because it would just exit through either openings 9 or 20 ***in the patient***, and not flow through the instrument lumen up to the outlet port which is located outside of the body of the patient as described in the present invention. There is not motivation to combine the seals of Reza with the lumens of Jacobsen, et al. because the purpose of the device of Jacobsen, et al. is ***to deliver or remove fluid from a patient.***

The downflow lumen of the present invention is described in the following paragraphs:

[0046] The second lumen a down flow lumen 34, extends from the body 14 and through the wall of the trocar 10. An outlet 40 opens proximate to the instrument lumen 30. The down flow lumen 34 is made of any resilient material that is fluid tight, and is capable of having a fluid flow there through.

[0047] The body 14 of the trocar 10 preferably includes an inlet port 36 fluidly connected to the down flow lumen 24. The inlet port 36 enables the flow of an inert fluid through the port 36 into the down flow lumen 40 within the trocar 10. Additionally, the body 14 includes at least one outlet port 38. The outlet port 38 allows air trapped within the body 14 and neck 12 of the trocar 10 to escape from the trocar 10.

[0048] In use, an inert fluid, such as saline, is flowed into the down flow lumen 34, via the inlet port 26, out the outlet port 40 proximate to the instrument lumen 30 of the trocar 10. The fluid contacts any substances, such as air bubbles, that are present within the instrument lumen 30 of the trocar 10. The air bubbles then flow with the

fluid up the instrument lumen 30 to the outlet port 38. In other words, fluid is constantly forcibly passed through the instrument lumen 30 of the trocar 10 such that any air bubbles found within the trocar 10 are captured within the fluid and the flow of the fluid carries the air bubbles away from the insertion end 16 of the trocar 10.

[0049] Of vital importance in surgery is that air not be allowed to enter the bloodstream of a patient. This is most critical when beating heart cardiac surgery is being performed because the insertion of oxygen into a blood stream can cause a fatal problem for the patient. Thus, the flowing of the fluid into the instrument lumen 30 of the trocar 10 enables air, and any other substances present in the trocar 10, to be removed from the patient, thereby preventing air or other foreign substances from entering the blood stream of a patient.

As defined in the presently amended independent claim 1, the downflow lumen is "extending from said body portion to an outlet port proximate to and coaxial with said instrument lumen and said body portion including an inlet port fluidly connected to said downflow lumen for enabling flow of an inert fluid from said downflow lumen into said instrument lumen about an instrument extending therethrough and out of an inlet port in said body portion."

The downflow lumen as defined above is critical to the function of the present invention, as the reason for the downflow lumen being present is to remove any harmful substances that can be present in the instrument lumen from entering the patient. Having extra openings in the lumen as shown in Jacobsen, et al. would defeat the purpose of including the downflow lumen in the present invention. Furthermore, none of the cited references disclose or suggest flowing an inert fluid in the downflow lumen into the instrument lumen and ***not out into a patient***. Thus, combining Yoon, Riza, et al., and Jacobsen, et al. would not result in the present invention.

Since neither the cited references alone or in combination with knowledge in the art suggest the currently claimed invention, it is consequently respectfully submitted that the claims are clearly patentable over the combination, even if the combination were to be applied in opposition to applicable law, and reconsideration of the rejection is respectfully requested.

Claims 4 stands rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,788,676 to Yoon in view of U.S. Patent No 5,993,471 to Riza, et al., and further in view of U.S. Patent No. 4,180,068 to Jacobsen, et al., and further in view of U.S. Patent No. 5,658,298 to Vincent, et al. Reconsideration of the rejection under 35 U.S.C. §103(a), as being unpatentable over Yoon in view of Riza, et al., Jacobsen, et al., and Vincent, et al. is respectfully requested.

As stated above, the combination of Yoon, Riza, et al., and Jacobsen, et al. does not result in the invention as claimed in the presently amended independent claims. Therefore, adding Vincent, et al. to this combination does not arrive at invention as defined in the dependent claims.

Since neither the cited references alone or in combination with knowledge in the art suggest the currently claimed invention, it is consequently respectfully submitted that the claims are clearly patentable over the combination, even if the combination were to be applied in opposition to applicable law, and reconsideration of the rejection is respectfully requested.

Claims 11-13 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,788,676 to Yoon in view of U.S. Patent No 5,993,471 to Riza, et al., and further in view of U.S. Patent No. 4,180,068 to Jacobsen, et al., and further in view of U.S. Patent No. 5,968,060 to Kellogg. Reconsideration of the rejection under 35 U.S.C. §103(a), as being unpatentable over Yoon in view of Riza, et al., Jacobsen, et al., and Kellogg is respectfully requested.

As stated above, the combination of Yoon, Riza, et al., and Jacobsen, et al. does not result in the invention as claimed in the presently amended independent claims. Therefore, adding Kellogg to this combination does not arrive at invention as defined in the dependent claims.

Since neither the cited references alone or in combination with knowledge in the art suggest the currently claimed invention, it is consequently respectfully submitted that the claims are clearly patentable over the combination, even if the combination were to be applied in opposition to applicable law, and reconsideration of the rejection is respectfully requested.

Claim 16 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Yoon in view of Riza, et al. and further in view of Jacobsen, et al., and in further view of U.S. Patent No 5,256,149 to Banik, et al. Reconsideration of the rejection under 35 U.S.C. §103(a), as being unpatentable over Yoon in view of Riza, et al., Jacobsen, et al., and Banik, et al. is respectfully requested.

As stated above, the combination of Yoon, Riza, et al., and Jacobsen, et al. does not result in the invention as claimed in the presently amended independent claims. Therefore, adding Banik, et al. to this combination does not arrive at invention as defined in the dependent claims.

Since neither the cited references alone or in combination with knowledge in the art suggest the currently claimed invention, it is consequently respectfully submitted that the claims are clearly patentable over the combination, even if the combination were to be applied in opposition to applicable law, and reconsideration of the rejection is respectfully requested.



Claims 17, 20, and 22-29 stand rejected under 35 U.S.C. § 103(a), as being unpatentable over Yoon in view of Riza, et al. and further in view of U.S. Patent Application Publication No. 2004/0191897 to Muschler. Specifically, the Office Action holds that the combination of Yoon and Riza, et al. fails to disclose flowing an inert fluid through a downflow lumen in the trocar, flowing the fluid through an outlet port of the downflow lumen, into an instrument lumen and up through the instrument lumen, thereby removing any substances in the instrument lumen and preventing the substances from entering the patient. The Office Action holds that Muschler discloses an apparatus including a trocar having irrigation means that control the delivery of saline or an inert fluid to the distal end of the apparatus, a downflow lumen through which the inert fluid flows through an outlet port, into and up through the instrument lumen by aspiration means which removes any substances in the instrument lumen and prevents the substances from entering the patient. Reconsideration of the rejection under 35 U.S.C. § 103(a), as being unpatentable over Yoon, Riza, et al. and Muschler, is respectfully requested.

Muschler discloses a device for harvesting bone marrow cells, blood, and bone fragments. Irrigation fluid can be dispensed through the lumen 42 and **out through the cutting bit 50**, and can be used to clear any bone or other tissue lodged in the cutting bit 50 or the distal end 64 of the cannula 60 (paragraph [0075]). In other words, the purpose of the inert fluid is to clear debris and then it exits through the cutting bit or distal end into the patient. Furthermore, as stated in paragraph [0073], the irrigation fluid can be used to aid in the aspiration of disrupted bone tissue, i.e. bone tissue that is outside the apparatus waiting to be taken up by the device. In another embodiment shown in Figure 12, irrigation fluid is supplied to the cutting tip via the lumen and assists in washing disrupted bone tissue into the opening 516 and into passage 76 in the cannula (paragraph [0100]). Thus, Muschler only discloses a device wherein inert or irrigation fluid is able to exit the device, and this is critical for harvesting bone marrow, blood and bone fragments, as the area that has been drilled generally requires aspiration and fluid in order to recover these particles. There would be no

reason to use the teachings of Muschler in combination with Yoon and Riza, et al. because there is no purpose to keeping the irrigation fluid just within the device of Muschler and not exposed to the patient. Therefore, none of the references alone or combined teach or suggest preventing substances from entering the patient as required by the independent claim 17.

Since neither the cited references alone or in combination with knowledge in the art suggest the currently claimed invention, it is consequently respectfully submitted that the claims are clearly patentable over the combination, even if the combination were to be applied in opposition to applicable law, and reconsideration of the rejection is respectfully requested.

Claims 18 and 19 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Yoon, Riza, et al., Muschler, and U.S. Patent No. 5,658,298 to Vincent et. al. The Office Action holds that James discloses all of the limitations previously discussed except for the method step of sealing the lumen. The Office Action holds that it would have been obvious to provide the trocar of James with sealing means as taught by Yoon. Reconsideration of the rejection under 35 U.S.C. §103(a), as being unpatentable over James in view of Yoon is respectfully requested.

As stated above, the combination of Yoon, Riza, et al., and Muschler does not disclose all of the required elements of the presently pending independent claims of having downflow lumens that prevent substances from entering the patient. Combining these references with Vincent, et al. does not make up for the deficiencies in the references.

Since neither the cited references alone or in combination with knowledge in the art suggest the currently claimed invention, it is consequently respectfully submitted that the claims are clearly patentable over the combination, even if the

combination were to be applied in opposition to applicable law, and reconsideration of the rejection is respectfully requested.

Claim 30 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Yoon, Riza, et al., Muschler, and further in view of Kellogg. The Office Action holds that Jacobsen, et al. fails to teach agitation means, but it would have been obvious to have provided James's trocar with vibrating means as taught by Kellogg. Reconsideration of the rejection under 35 U.S.C. §103(a), as being unpatentable over Yoon, Riza, et al., and Muschler, in view of Kellogg is respectfully requested.

As stated above, the combination of Yoon, Riza, et al., and Muschler does not disclose all of the required elements of the presently pending independent claims of having downflow lumens that prevent substances from entering the patient. Combining these references with Kellogg does not make up for the deficiencies in the references.

Since neither the cited references alone or in combination with knowledge in the art suggest the currently claimed invention, it is consequently respectfully submitted that the claims are clearly patentable over the combination, even if the combination were to be applied in opposition to applicable law, and reconsideration of the rejection is respectfully requested.

The remaining dependent claims not specifically discussed herein are ultimately dependent upon the independent claims. References as applied against these dependent claims do not make up for the deficiencies of those references as discussed above, and the prior art references do not disclose the characterizing features of the independent claims discussed above. Hence, it is respectfully submitted that all of the pending claims are patentable over the prior art.

It is respectfully requested that the present amendment be entered in order to place the application in condition for allowance or at least in better condition for appeal. The application is placed in condition for allowance as it addresses and resolves each and every issue that remains pending. Claims have been amended to clearly distinguish over the prior art. The application is made at least in better condition for appeal as the amendment removes many issues thereby simplifying the issues on appeal. That is, each and every rejection has been overcome exactly as suggest in the Office Action. Further, the claims have been amended to more specifically define the invention while raising no new issues that would require any further searching. Rather, the amendments have been made in view of comments made in the Office Action that clearly distinguish the presently pending claims over the cited prior art. Hence, it is respectfully requested that the amendment be entered.

The Commissioner is authorized to charge any fee or credit any overpayment in connection with this communication to our Deposit Account No. 11-1449.

Respectfully submitted,

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